DATE: 30 Sep 03

USAMMDA INFORMATION PAPER

PRODUCT: DENGUE TETRAVALENT VACCINE

DESCRIPTION: The Dengue Tetravalent Vaccine (DTV) is a live-attenuated virus vaccine that will protect U.S. Forces against dengue fever (DF), and the more severe dengue hemorrhagic fever (DHF). Dengue is a threat in many tropical and subtropical regions of the world where service members are stationed or may deploy. Transmitted by mosquitoes, DF is caused by any of the four known dengue viruses. Worldwide, fifty to one hundred million people are infected annually, with an estimated two million DHF cases and thirty-five thousand deaths. Dengue epidemics are explosive with the potential to rapidly incapacitate large numbers of personnel. Acute, debilitating illness is characterized by 4-7 days of fever, severe headache, muscle, joint and eye pain. Convalescence and hospitalization may be prolonged, lasting several weeks. Individuals infected with one dengue virus are at increased risk for developing the often-fatal DHF if a different dengue virus subsequently infects them; hence the requirement for the vaccine to protect long-term against all four dengue viruses.

PROGRAM RELEVANCE to the ARMY: The DTV supports the core Mission of the Army, Army Transformation, and Force Operating Capability MD 97-007 (Preventive Medicine). The DTV increases the survivability and sustainability of the force in regions of the world where dengue is endemic, thereby directly enhancing Force XXI and Objective Force operations. The DTV is key to maintaining OPTEMPO by providing protection for individual personnel, thus enabling continued operations despite the presence of endemic disease.

ISSUES/ACTIONS:

- The Thai Ministry of Public Health requires DTV safety testing in 5-10 children between 5 and 10 years of age before infants can be vaccinated. A Phase 1 safety and immunogenicity study in Thai children aged 5 to 10 years began 16 August 2003. If an acceptable safety profile is achieved, a Phase 1 safety and immunogenicity study in Thai infants will be conducted in 2004.
- The immune response with the current vaccine formulation is less than optimal. To improve immunity, studies are planned to 1) add a third dose, 2) change the route of administration from subcutaneous to intradermal, and 3) test a new vaccine formulation. A Phase 1 study in US adult volunteers is underway to assess addition of a third vaccine dose and evaluate an intradermal route of administration. A Phase 1 safety and immunogenicity study of a new vaccine formulation is scheduled to begin 8 September 2003
- The Operational Requirements Document (ORD) for the DTV has been re-written to satisfy new TRADOC and DA requirements. A final draft document is under review currently by the major stakeholders.

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SCHEDULE:

MS I	3QFY00
MS B	1QFY07
MS FRP	3QFY11

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